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09/932,128	08/16/2001	Juan Yguerabide	11032-021	5342

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EXAMINER

YANG, NELSON C

ART UNIT PAPER NUMBER

1641

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/932,128	YGUERABIDE ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-52, 55, 60-63, 66, 68, 71-73, 80, 84, 88 and 166-215 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-52, 55, 60-63, 66, 68, 71-73, 80, 84, 88 and 166-215 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/5/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 49-52, 55, 60-63, 66, 68, 71-73, 76, 80, 84, and 88 and addition of claims 166-216 are acknowledged and have been entered.
2. Applicant's cancellation of claims 53, 54, 56-59, 64, 65, 67, 69, 70, 74, 75, 77-79, 81-83, 85-87, 89-165 is acknowledged and has been entered.
3. Claims 49-52, 55, 60-63, 66, 68, 71-73, 80, 84, 88, 166-215 are currently pending

Election/Restrictions

4. Applicant's election with traverse of group I, claims 49-61, 63-66, 68, 71-78, 85-88 in the reply filed on April 23, 2004 is acknowledged. The traversal is on the ground(s) that claims 62, 80, 84 and new claims 166-216 fall within the elected group of the invention of group I. This was found persuasive and therefore the restriction toward claims 62, 80, 84 and new claims 166-216 are withdrawn.
5. With respect to applicant's traversal regarding the remainder of the groups, because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Although applicant argue that the groups of claims are an intricate web of knowledge and continuity of effort, applicant has not pointed out how they are an intricate web of knowledge and continuity of effort. Furthermore, applicant has cancelled the non-elected claims. Therefore, the restriction requirement is maintained.
6. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

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7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 49-52, 55, 60-63, 66, 68, 71-73, 76, 80, 84, 88, 166-212 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 49, 182, recite the limitation of particles having a size between 1 and 500 nm inclusive. However, it is unclear what the size is referring to, whether it refers to the circumference, the diameter, the volume, surface area of the particles, or something else entirely.

10. Claim 49 recites the limitation that when each population is on a surface at a particle density of less than 0.1 particles per μm^2 the color scattered light scattered by at least 90% of said particles of each said population is indistinguishable to the human eye when viewed with less than 500 times magnification and without electronic amplification. It is unclear what physical or structural characteristics of the particles would be necessary in order for color scattered light scattered by at least 90% of said particles of each said population to be indistinguishable to the human eye when viewed with less than 500 times magnification and without electronic amplification, or if this is a result of the population of particles being on a surface and/or being illuminated by white light.

11. With respect to claim 60, 88, 182, it is not entirely clear how the coefficient of variation in size would be calculated, rendering the claims indefinite. Currently, it is assumed that the coefficient of variation merely refers to the maximum % difference in

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diameter between particles in a population with average particle diameter of particles in the population.

12. The term "significantly" in claim 50 is a relative term which renders the claim indefinite. The term "significantly" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear how much interaction would be considered a significant amount of interaction, rendering it unclear what materials would be encompassed by the at least one additional material.

13. With respect to claim 60, it is unclear if the limitation that the variation of size is less than 5% refers to variation between populations, or within populations.

14. The term "about" in claim 76, 80, 173-175, 178, 180, 181, 191-193, 200-204 is a relative term which renders the claim indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In particular, it is unclear if the coefficient of variation disclosed by applicant is intended to be used to determine what would be considered "about" a certain value, and if so, which coefficient of variation would be used (5%, 10%, etc.), and how it would be used to determine the range that would be encompassed by the term "about".

15. With respect to claims 167, 184, it is unclear what physical or structural characteristics would be necessary in order for the color of the scattered light scattered by two or more populations to be distinguishably different, rendering the claims unclear and indefinite.

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16. The term "distinguishably" in claim 167 is a relative term which renders the claim indefinite. The term "distinguishably" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear whether intensity or wavelength or quantity is to be used as a basis of measurement, or if something else is to be considered.

17. With respect to claim 167, it is unclear whether the binding agent of the populations of particles is capable of binding to a variety of different analytes, or if the binding agent of each population binds to a different analyte.

18. With respect to claim 215, it is unclear what materials would provide chemical stability, rendering the claim indefinite.

19. The remaining claims are indefinite due to their dependence on an indefinite claim.

Claim Rejections - 35 USC § 112

20. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

21. Claims 174, 175 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Although support can be found for gold or silver

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coatings that are greater than 19 nm, support was not found for thinner gold or silver coatings. Although support was found for 1-2 nm coatings, these coatings referred to magnetic or ferroelectric coatings (p.84, lines 1-18).

Claim Rejections - 35 USC § 102

22. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

23. Claims 49-52, 55, 61-63, 66, 68, 76, 80, 84, 166-173, 176-179 are rejected under 35 U.S.C. 102(b) as being anticipated by Mroczkowski et al [US 5,137,827].

With respect to claims 49, 55, 61, 63, 66, 76, 80, 84, 166-173, 176-179, Mroczkowski et al teach particles made from an electrically conductive metal such as gold or silver or plastic particles with a conductive metal coating such as gold (column 9, lines 15-25) with diameters of 0.01-500 microns. Mroczkowski et al further teach that the particles comprise an additional material such as antibodies (column 9, lines 1-5).

The limitation that “when each said population is on a surface at a particle density of less than 0.1 particles per μm^2 and illuminated by white light, the color of scattered light scattered by at least 90% of said particles of each said population is indistinguishable to the human eye when viewed with less than 500 times magnification and without electronic amplification” is considered to be an intended use of the one or

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more populations of scattered light-detectable particles, and therefore has not been given any patentable weight.

24. With respect to claims 50-52, 68, Mrockowski et al further teach that the particles comprise an additional material such as antibodies (column 9, lines 1-5). Although Mrockowski et al do not specifically recite that the material does not significantly interact with light in the visible region of the spectrum, a person of ordinary skill in the art would have known that materials such as protein would not significantly interact with light in the visible region of the spectrum.

25. With respect to claims 62, Mrockowski et al further teach a metal overcoating comprising a material such as silver (column 11, lines 31-40).

26. Claims 49-52, 55, 60, 63, 66, 71-73, 76, 80, 84, 88, 166-173, 176-179, 182-191, 196, 198, 205-215 are rejected under 35 U.S.C. 102(b) as being anticipated by Rembaum et al [US 4,929,400].

With respect to claims 49, 55, 60, 63, 66, 76, 80, 84, 88, 166, 168-173, 176-179, 182, 183, 185-191, 196, 198, 205-208, 212-215, Rembaum et al teach microspheres created from polymers, proteins, waxes, starches, glasses and metals (column 3, lines 40-45), and further comprising materials such as silver, gold, and polyHEMA and having precise size range with diameters below 1000 Angstroms (column 8, lines 41-54, lines 55-69), varying no more than plus or minus 5% (column 3, lines 65-68).

The limitation that “when each said population is on a surface at a particle density of less than 0.1 particles per μm^2 and illuminated by white light, the color of scattered light scattered by at least 90% of said particles of each said population is

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indistinguishable to the human eye when viewed with less than 500 times magnification and without electronic amplification” is considered to be an intended use of the one or more populations of scattered light-detectable particles, and therefore has not been given any patentable weight.

27. With respect to claims 50-52, Rembaum et al teach microspheres created from polymers, proteins, waxes, starches, glasses and metals (column 3, lines 40-45). Although Rembaum et al do not specifically recite that the material does not significantly interact with light in the visible region of the spectrum, a person of ordinary skill in the art would have known that materials such as protein would not significantly interact with light in the visible region of the spectrum.

28. With respect to claims 71-73, 209-211, magnetic fillers can be incorporated into the particles used to form the microspheres (column 3, lines 45-50).

29. Claims 48-52, 55, 61-63, 68, 71-73, 76, 80, 84, 166-173, 176-179 are rejected under 35 U.S.C. 102(b) as being anticipated by Margel [US 4,624,923].

With respect to claims 49, 55, 61-63, 68, 76, 80, 84, 166, 173, 176-179 Margel teaches populations of polyaldehyde microspheres coated with silver or gold (column 2, lines 15-30), where the sizes of the populations include 0.4 μ , 0.1 μ , 0.05 μ diameters (column 11-13, examples 8-25), and further comprising a drug, antibody, antigen, enzyme or other protein (claim 7).

30. With respect to claims 50-52, 167-172 Margel teaches that the microspheres further comprise a drug, antibody, antigen, enzyme or other protein (claim 7). Although Margel does not specifically recite that the material is a base material or does not

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significantly interact with light in the visible region of the spectrum, a person of ordinary skill in the art would have known that materials such as protein would be base materials and would not significantly interact with light in the visible region of the spectrum.

31. With respect to claim 71-73, the microspheres may be magnetic (column 2, lines 23-25).

32. Claims 49-52, 55, 62, 66, 68, 76, 80, 84, 166-173, 176-179, 181, are rejected under 35 U.S.C. 102(e) as being anticipated by Tarcha [US 5,567,628].

33. With respect to claims 49, 55, 66, 76, 80, 84, 173, Tarcha et al teach gold colloids with diameters 50-60 nm (column 19, lines 33-47) and further comprising antibodies (column 23, lines 20-45) and polymer enhancers (column 9, lines 18-26), and can also comprise silver coatings (column 17-18, example 5).

34. With respect to claims 50-52, 68, 166-172, 176-179, 181, Tarcha et al teach that the colloids may be labeled with anti-biotin antibodies (column 23, lines 20-45).

Claim Rejections - 35 USC § 103

35. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

36. Claims 60, 88, 180, 182-184, 186-191, 194-199, 201-208, 212-216, rejected under 35 U.S.C. 103(a) as being unpatentable over Tarcha [US 5,567,628].

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With respect to claim 180, Tarcha et al teach gold colloids with diameters 50-60 nm (column 19, lines 33-47) and further comprising anti-biotin antibodies (column 23, lines 20-45). Tarcha do not teach gold colloids with diameters of 80 nm.

It would, however, have been obvious to one having ordinary skill in the art at the time the invention was made to have colloids with diameters of 80 nm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

37. With respect to claims 60, 88, 182-184, 186-191, 194-199, 201, 202, 205-208, 212-215, Tarcha et al teach gold colloids with diameters 50-60 nm (column 19, lines 33-47) and further comprising antibodies (column 23, lines 20-45) and polymer enhancers (column 9, lines 18-26) and stabilizers (column 10, lines 22-25).

Tarcha et al fail to disclose the limitation that the population of microspheres is characterized by a coefficient of variation of less than 5%. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a coefficient of variation of less than 5%, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

38. With respect to claims 203-204, Tarcha et al teach that the colloids may be labeled with anti-biotin antibodies (column 23, lines 20-45).

Although Tarcha et al do not teach colloids with diameters of 80 nm, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have colloids with diameters of 80 nm, since it has been held that where the

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general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

39. With respect to claim 216, Tarcha do not teach that the populations comprise at least 10^5 to 10^{13} particles. It would, however, have been obvious to one having ordinary skill in the art at the time the invention was made to have populations comprising at least 10^5 to 10^{13} particles, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

40. Claims 60, 88, 174, 175, 182-184, 193, 196-202, 205-208, 212-216 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mroczkowski et al [US 5,137,827].

With respect to claims 60, 88, 182-184, 196-198, 201, 202, 205-208, 212-214, Mroczkowski et al teach particles made from an electrically conductive metal such as gold or silver or plastic particles with a conductive metal coating such as gold (column 9, lines 15-25) with diameters of 0.01-500 microns. Mroczkowski et al further teach that the particles comprise an additional material such as antibodies (column 9, lines 1-5).

Mroczkowski et al fail to disclose the limitation that the population of microspheres is characterized by a coefficient of variation of less than 5%. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a coefficient of variation of less than 5%, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

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41. With respect to claims 199, Mrockowski et al further teach a metal overcoating comprising a material such as silver (column 11, lines 31-40).
42. With respect to claims 174, 175, 193, 200, Mroczkowski et al fail to disclose the limitation of the thickness of the coatings being about 0.5, 0.8, 1.5, 2, 4, 5, 6, 10, 12, or 20 nm. It would have been obvious to one having ordinary skill in the art at the time the invention was made for the thickness of the coatings being about 0.5, 1.5, 2, 4, 5, 6, 10, 12, or 20 nm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.
43. With respect to claim 215, Mroczkowski et al teach the use of a stabilizer (column 9, lines 34-38).
44. With respect to claim 216, Mrockowski et al do not teach that the populations comprise at least 10^5 to 10^{13} particles. It would, however, have been obvious to one having ordinary skill in the art at the time the invention was made to have populations comprising at least 10^5 to 10^{13} particles, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.
45. Claims 181-182, 203-204 are rejected under 35 U.S.C. 103(a) as being unpatentable over Margel [US 4,624,923] in view of Tarcha et al [US 5,567,628].
- Mroczkowski et al teach particles made from an electrically conductive metal such as gold or silver or plastic particles with a conductive metal coating such as gold. Mrockowski et al further teach that the particles comprise an additional material such as

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antibodies. Mrockowski et al fail to teach that the antibodies are anti-biotin, anti-fluorescein or anti-digoxinin antibodies.

Tarcha et al, however teach the use of anti-biotin antibodies as a means for attaching biotinylated antibodies [column 23, lines 20-45]. Therefore it would have been obvious in the invention of Mrockowski et al to have microspheres comprising anti-biotin antibodies, as suggested by Tarcha et al, in order to attach biotinylated antibodies.

46. Claims 60, 88, 174, 175, 182-184, 193, 196-202, 205-216 rejected under 35 U.S.C. 103(a) as being unpatentable over Margel [US 4,624,923].

With respect to claims 60, 88, 182-184, 196-202, 205-208, 212-215 Margel teaches populations of polyaldehyde microspheres coated with silver or gold (column 2, lines 15-30), comprising beads with diameters between .01 μ and 100 μ (column 4, examples 25-30), and further comprising a drug, antibody, antigen, enzyme or other protein (claim 7).

Margel fails to disclose the limitation that the population of microspheres is characterized by a coefficient of variation of less than 5%. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a coefficient of variation of less than 5%, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

47. With respect to claims 174, 175, 193, 200, Margel fails to disclose the limitation of the thickness of the coatings being about 0.5, 0.8, 1.5, 2, 4, 5, 6, 10, 12, or 20 nm. It would have been obvious to one having ordinary skill in the art at the time the invention

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was made for the thickness of the coatings being about 0.5, 1.5, 2, 4, 5, 6, 10, 12, or 20 nm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

48. With respect to claim 209-211, the microspheres may be magnetic (column 2, lines 23-25).

49. With respect to claim 216, Margel teaches 50 mg of microspheres at concentrations of 2.9 millimole/g microspheres.

50. Claims 181, 182, 203, 204 are rejected under 35 U.S.C. 103(a) as being unpatentable over Margel [US 4,624,934] in view of Tarcha et al [US 5,567,628].

Margel discloses populations of polyaldehyde microspheres coated with silver or gold and further comprising antibodies. Margel fails to teach that the antibodies are anti-biotin, anti-fluorescein or anti-digoxinin antibodies.

Tarcha et al, however teach the use of anti-biotin antibodies as a means for attaching biotinylated antibodies (column 23, lines 20-45). Therefore it would have been obvious in the invention of Margel to have microspheres comprising anti-biotin antibodies, as suggested by Tarcha et al, in order to attach biotinylated antibodies.

Conclusion

51. No claims are allowed.

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52. The following references are also cited as art of interest: Klabunde [US 4,877,647], Parsons et al [US 5,518,887], Powell et al [US 5,728,590], Gustafson et al [US 4,876,208] teach the use of metallic particles.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826.

The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Examiner
Art Unit 1641



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06/12/04